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Guidance for the Reregistration of Pesticide Products Containing Diphenamid as the Active Ingredient

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EPA

Guidance for the Reregistration of Pesticide Products Containing Diphenamid as the Active Ingredient

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U.S. DEPARTMENT OF COMMERCE
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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

DIPHENAMID

AS THE ACTIVE INGREDIENT

CHEMICAL CODE: 036601
CAS NUMBER: 957-51-7
CASE NUMBER: 0269

June 24, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

1. The Agency: U.S Environmental Protection Agency/EPA
2. ADI: Acceptable daily intake (mg/kg/day) of a pesticide by an individual weighing 60 kilograms
3. A.I.: Pesticide active ingredient
4. CAS: Chemical Abstract Society (number)
5. CSF: Confidential Statement of Formula
6. DCI: Data Call-In Notice
7. EPs: End-Use pesticide products
8. EUP: Experimental Use Permit
9. FIFRA: Federal Insecticide, Fungicide, Rodenticide Act (As amended)
10. LC_{50}: (median lethal concentration) a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).
11. LD_{50}: (median lethal dose) a statistically derived single dose that can be expected to cause death in 50% of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).
12. LEL: Lowest Effect Level
13. MBYP: Meat byproducts of cattle, goats, hogs, horses and sheep.
14. MPs: Manufacturing-Use pesticide products
15. MPI: Maximum permitted intake of a pesticide in XX mg/day for a 60 kg individual.
16. NOEL: No Observed Effect Level
17. NPDES Permit: National Pollutant Discharge Elimination System
18. MRID: Master Record Indentification (number) - EPA's system of tracking studies used in support of registrations.

19. OES: Office of Endangered Species, U.S. Dept. of the Interior

20. PADI: a provisional/temporary ADI

21. RAC's: Raw agricultural commodities

22. Technical: Technical grade of the active ingredient

23. 40 CFR: Title 40, Code of Federal Regulations

24. TMRC: Theoretical Maximum Residue Contribution for a pesticide in the daily diet is based on the total tolerances in addition to a daily food intake of X.X kg = X.X mg/kg.

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be requested from: Information Services Section (TS-768C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Room 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202 (telephone (703) 557-4453).

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data that EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Table A in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of chemical

The following chemical is covered by this Registration Standard:

Common name:	Diphenamid
Chemical name:	N,N-dimethyldiphenylacetamide
CAS Number:	957-51-7
OPP (Shaughnessy) Number:	036601
Empirical Formula:	$C_{16}H_{17}NO$
Trade Names:	Difenamid, Dymid, Enide®, A-831010, L-34-314
Chemical Family:	Acetamide
Pesticide Type:	Herbicide
Year of Initial Registration:	1964
Registrants of Technical Products:	Nor-Am Chemical Co.

Description of physical characteristics of chemical:

Diphenamid is a white to off white granular solid with a sweet aromatic odor at room temperature, its melting point is 133.8-135.4° C, and its molecular weight is 239.3. Its solubility in water is 0.26 g/liter at 25°C.

B. Use Profile

Type of pesticide:	Selective preemergent herbicide,
Pests controlled:	Annual grasses, broadleaf weeds
Registered Uses:	Field, bush, vine & vegetable crops, fruit, citrus fruit, cotton, greenhouse & ornamental plants, and turf,
Predominant uses:	Tomatoes, tobacco, sweet potatoes potatoes, caneberries & peppers,
Mode of activity:	Inhibition of terminal leaf and root growth or seed germination,
Single active ingredient (a.i.)	97% technical,
Formulations:	90%, 80% & 50% (a.i.) wettable powder; 5% & 1.42% (a.i.) granular; 42.5% & 15.4% (a.i.) flowable concentrates,
Methods of application:	Primarily applied as broadcast or banded spray by ground or aerial equipment,
Application Rates:	Terrestrial food crops: 2.0 to 9.0 lb. a.i. per acre, Terrestrial non-food crops: 2.0 to 6.0 lb. a.i. per acre, ornamentals: 0.50 to 1.25 lb. a.i. per acre.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all of the data submitted to support the registration of diphenamid, as well as open literature information relevant to this compound. Based on the review of these data, the Agency has reached the following conclusions.

Diphenamid related effects include increased liver weights and slight histological changes in a chronic toxicity study in dogs. Except for mild liver reactions in weanlings, this chemical does not induce reproductive effects in rats. This pesticide has shown low acute oral and dermal toxicity in test animals and it is not an eye irritant. It is low in avian toxicity and slightly to moderately toxic to fish and aquatic invertebrates.

Although the present data base for diphenamid does not indicate major toxicological concerns, there are toxicology data gaps: including acute inhalation toxicity, primary dermal irritation, dermal sensitization, subchronic dermal toxicity (21-day), chronic toxicity (rat), oncogenicity in two species, teratology in two species, mutagenicity and general metabolism studies.

In addition, the environmental fate, product chemistry, and the metabolism in food crops, in ruminants and poultry for this compound have not been characterized.

B. TOXICOLOGY

1. In a 2-year dog feeding study, males and females were offered diets containing 0, 120, 400, and 1200 ppm technical diphenamid in the diet for 103 weeks. The only compound-related effects included slightly increased liver weights and slightly increased portal macrophages and/or fibroblasts in the livers of the dogs in the 400 and 1200 ppm dose group. The no-observed-effect level (NOEL) was determined to be 120 ppm (3 mg/kg/day) in the diet.

   Available data are sufficient to satisfy the data requirements for chronic toxicity study in the nonrodent (dog) only.

2. A rat feeding study was not adequate to assess chronic toxicity or oncogenicity. A chronic toxicity study and oncogenicity study in rats are required. Also, a second species oncogenicity study (mouse) is ongoing and is expected to be completed in June 1988.

3. Technical diphenamid was fed at dosage levels of 0, 10, and 30 mg/kg/day to rats of both sexes in a three generation reproduction study. The only compound-related effects observed were mild liver reactions in the weanlings of the F3 generation from the high dose group (30 mg/kg/day). Therefore, the NOEL for fetal effects was determined to be 10 mg/kg/day (200 ppm). Since the data demonstrated absence of reproduction performance effects in treated animals at all the dose levels, the NOEL for reproductive effects was determined to be greater than 600 ppm (30 mg/kg/day) in the diet. Sufficient data are available to satisfy the data requirements for a reproduction study in the rat.

4. No teratology studies are available for technical diphenamid. Teratology studies in the rat and the rabbit are required.

5. Diphenamid technical exhibited low acute oral toxicity [Category III: 1,373 mg/kg (rats, both sexes)], low acute dermal toxicity [Category III: >6,320 mg/kg (rabbits, both sexes)] to mammals. It was not an eye irritant in the primary eye irritation study:[Category IV - No irritation with 0.1 ml solution (rabbits)].

C. OTHER SCIENCE FINDINGS

1. Human Exposure

Major routes of exposure: Applicators (mixer/loader) handling this pesticide would be exposed primarily through skin contact and inhalation.

2. Physiological & Biochemical Chracteristics:

Translocation: Diphenamid is absorbed by the roots and translocated through the roots, stem, and leaves.

Mechanism of pesticidal action: It inhibits growth in terminal leaves and roots.

Metabolism & Persistence in Plants & Animals: The available data are inadequate to evaluate the persistence of diphenamid in plants and animals.

3. Environmental Fate

The Agency does not have sufficient data to fully assess the environmental fate of diphenamid.

a. Ground Water

A ground water Data Call-In Notice was issued for diphenamid. The data received were insufficient to fully assess the leaching potential of parent compound and metabolites in a variety of soils. However, available studies indicate that this compound is mobile in a silty clay loam soil, and is relatively stable to hydrolysis and may leach to ground water supplies.

b. Degradation

The Agency does not have sufficient data to fully assess the degradation of diphenamid.

c. Forestry Uses

Since the registrant has voluntarily deleted the forestry use pattern for diphenamid products, an anaerobic aquatic metabolism and a forestry dissipation study which would have been required under forestry uses will not be required in this Standard.

4. Ecological Effects

There is sufficient information to characterize technical diphenamid as slightly toxic to freshwater invertebrates: Daphnia magna (LC_{50} of 58.0 ppm). There is sufficient information to characterize formulated diphenamid as having very low toxicity on avian dietary basis: Bobwhite quail (LC_{50} of 18,000 and Mallard duck (LC_{50} of 30,000 ppm). However, an avian single-dose oral toxicity study and an avian dietary toxicity study in two species using technical diphenamid are required. There is sufficient information to characterize formulated diphenamid as being slightly toxic to warmwater fish: Bluegill (LC_{50} of 32.0 ppm) and moderately toxic to coldwater fish: Rainbow trout (LC_{50} of 1.2 ppm). However, a freshwater fish toxicity study in two species using technical diphenamid is required. In an acute contact study, diphenamid was shown to be very low in toxicity to honey bees.

Hazard assessments were conducted for terrestrial and aquatic organisms in which hypothetical environmental concentrations were compared to lethal concentrations (LC_{50}) and lethal dosages (LD_{50}) of the pesticide. Acute concerns were not triggered for mammals, birds, or fish.

Since the registrant has voluntarily deleted the forestry use pattern for diphenamid products, endangered species labeling which would have been required under forestry uses will not be required in this Standard.

D. TOLERANCE REASSESSMENT

According to 40 CFR 180.230, tolerances for diphenamid have been approved for the raw agricultural commodities (RAC's) listed below.

Crop	Tolerance(ppm)
Apples	0.10
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, mbyp	0.05
Cottonseed	0.10
Cotton forage	0.20
Fruiting vegetables	0.10
Goat, fat	0.05
Goat, meat	0.05
Goat, mbyp	0.05
Hogs, fat	0.05
Hogs, meat	0.05
Hogs, mbyp	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, mbyp	0.05
Milk	0.01
Okra	0.10
Peaches	0.10
Peanuts	0.10
Peanut, hay & forage	2.00
Peanut hulls	0.50
Potatoes	1.00
Raspberries	1.00
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, mbyp	0.05
Strawberries	1.00
Soybeans	0.10
Soybean, hay & forage	0.50
Sweet potatoes	0.10

The Provisional Acceptable Daily Intake (PADI) for diphenamid is based on the 103 week dog feeding study with a NOEL of 120 ppm (3 mg/kg/day). Other toxicology data considered in suport of these tolerances include a 3-generation rat reproduction study indicating that reproductive performance was not affected at dietary intake up to and including 30 mg/kg/day. Utilizing a safety factor of 100, the PADI was calculated to be .03 mg/kg/day.

The Agency examined the dietary burden of diphenamid using the Tolerance Assessment System (TAS), a dietary exposure data base. TAS allows the Agency, using either known residue levels or tolerance levels in raw agricultural commodities to determine the average and range of exposure to pesticide residues for the general population and twenty two subpopulations based on known patterns of food consumption. The theoretical dietary exposure expressed as a percentage of PADI utilized by the Theoretical Maximum Residue Contribution (TMRC) ranged from 3.8% to 11.8% of the PADI for various subgroups with 5.6% being the U.S. population average.

Additional data are required for plant and animal metabolism, analytical methods, and storage stability. Processing studies are required for potatoes, soybeans, tomatoes, apples, cottonseed and peanuts. Since the data required for individual commodities are dependent on metabolism data, the Agency recommends that metabolism data be obtained and submitted prior to any required residue data.

There is a Canadian tolerance of 1.0 ppm for diphenamid residues in or on strawberries, but no Canadian tolerances exist for residues of diphenamid on the other raw agicultural commodities listed in 40 CFR 180.230. There are no Mexican tolerances or Codex Maximum Residue Levels for residues of diphenamid on the raw agicultural commodities listed in 40 CFR 180.230.

Existing tolerances for soybean hay and forage; and peanut hay are adequately supported by data. Therefore, a proposal to remove the grazing and feeding restrictions currently in effect for diphenamid products in soybeans and peanuts would be approved by the Agency.

Reported Pesticide Incidences

The Pesticide Incident Monitoring System (PIMS) does not have any incident involving diphenamid at this time. Based upon data from California, five incidences indicating skin or eye irritation occurred from 1981 through 1985. Although four of the incidences involved applicators and one involved a non applicator, none of these cases required hospitalization.

E. SUMMARY OF LABEL CHANGES AND DATA GAPS

The Agency has determined that label revisions must be made in the following areas (See Section D, Part IV).

- Environmental Precautions
- Ecological Effects

The Agency has identified data necessary to evaluate the environmental and human risks associated with the use of diphenamid. These data must be developed in order to maintain registrations of products or register new products containing diphenamid. The following table summarizes the data gaps, including product chemistry information. Please note that this is only a summary and details can be obtained by referring to Table A.

Summary of Data Gaps - Diphenamid

158.120 Product Chemistry

All of the Product Chemistry data are required.

158.125 Residue Chemistry:

171-4 Nature of Residue (Plant & Animal Metabolism)
171-4 Residue Analytical Methods
171-4 Storage Stability
171-4 Residue Studies on Crops
171-4 Residue Studies on Processed Food/Feed Commodities

158.135 Toxicology:

81-3	Acute Inhalation Toxicity (Rat)
81-5	Primary Dermal Irritation (Rabbit)
81-6	Dermal Sensitization (Guinea pig)
82-2	Subchronic Dermal (21-day)
83-1	Chronic Toxicity (Rat)
83-2	Oncogencity (Two species)
83-3	Teratogenicity (Two species)
84-2	Mutagenicity
85-1	Metabolism

158.130 Environmental Fate

161-2	Photodegradation in Water
161-3	Photodegradation in Soil
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism

158.130 Environmental Fate

163-1	Mobility Studies-Leaching & Adsorption/ Desorption
163-2	Mobility Studies-Volatility (Lab)
164-1	Soil Dissipation
165-1	Rotational Crops (Confined)
165-4	Accumulation in Fish

158.145 Wildlife and Aquatic Organisms

71-1	Avian Acute Oral Toxicity
71-2	Avian Dietary Toxicity (Two species)
72-1	Freshwater Fish Acute Toxicity (Two species)
122-2	Aquatic Plant Growth

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions

Based on a review and evaluation of all available data and other relevant information on the herbicide diphenamid, the Agency has reached the following determinations.

1. The Agency will not place diphenamid in Special Review.

Rationale: Diphenamid does not exceed the risk criteria for adverse effects in 40 CFR, Section 154.7.

Available data indicate that Diphenamid does not pose a risk of serious acute injury to humans, avian species and aquatic organisms. In a chronic toxicity study of diphenamid in dogs, data indicated no adverse chronic liver effects at the 400 ppm (10 mg/kg/day) dosage level. Except for mild liver reactions in weanlings in the third generation of a reproduction study in rats, this compound does not induce reproductive effects in rats.

2. The Agency has determined that certain toxicological studies are required to support the reregistration of diphenamid products.

Rationale: The Agency does not have the following data on diphenamid which are required to meet Agency guidelines for toxicological testing necessary to support its registration: acute inhalation toxicity, primary dermal irritation, dermal sensitization, subchronic dermal (21-day), chronic toxicity in rats, oncogenicity in two species, teratology in two species, mutagenicity and and metabolism studies.

3. The Agency has determined that present precautionary statements for persons handling or applying diphenamid products are sufficient for the labels of manufacturing-use and end-use products.

Rationale: Available data indicate that diphenamid causes low acute oral (Category III) and acute dermal (Category III) toxicity in test animals and it is not an eye irritant (Category IV). The labeling of these products contains statements that provide precautionary measures to ensure safe handling of the pesticide products and provides the user with first aid instructions.

4. The Agency will require certain environmental fate data.

Rationale: The Agency does not have the following environmental fate data necessary to support the reregistration of diphenamid: photodegradation in water and soil, mobility (leaching & adsorption/desorption) mobility [volatility (lab)], soil dissipation, rotational crops (confined) and accumulation in fish studies.

5. The Agency has determined that certain groundwater data are required.

Rationale: The Agency evaluated the data submitted in response to the May 1984, Ground Water Data Call-In for Diphenamid, and found them to be inadequate to fully assess the potential of diphenamid to reach ground water supplies.

However, available data indicate that diphenamid is mobile in a silty clay-loam soil, and relatively stable to hydrolysis, and may leach to ground water.

The necessary environmental fate data (aerobic and anaerobic metabolism studies) are being repeated at the present time. The Agency expects to receive these data by July 1987. Until these data are received and found acceptable by the Agency, data gaps for ground water exist.

6. The Agency has determined that reentry data are not required for diphenamid at this time.

Rationale: The low acute toxicity of this chemical does not warrant significant concern about exposure of workers reentering treated areas, according to the criteria in 40 CFR Part 158.140. Diphenamid has been determined to be low in acute oral, and dermal toxicity, and it is not an eye irritant.

7. The Agency has determined that certain residue chemistry data are required.

Rationale: The Agency does not have the following residue chemistry data necessary to support the reregistration of diphenamid: plant and animal metabolism, analytical methods, storage stability, and processing studies for potatoes, soybeans, tomatoes, apples, cottonseed and peanuts.

8. The Agency has determined that grazing and feeding restrictions for soybean hay and forage, and peanut hay are not required for diphenamid products.

   Rationale: Existing tolerances for soybean hay and forage; and peanut hay are adequately supported by residue chemistry data. Therefore, EPA will approve removing the grazing and feeding restrictions currently in effect for soybeans and peanuts if the registrants propose it.

9. The Agency has determined that endangered species labeling is not required in this standard.

   Rationale: The registrant has voluntarily deleted the forestry use pattern for diphenamid products. Therefore, endangered species labeling which would have been required under forestry uses will not be required in this standard.

10. The available data indicate that this pesticide, when applied at recommended rates, does not present unreasonable hazards to birds.

    Rationale: Existing studies on a formulation of this chemical indicate that its dietary toxicity to avian species is very low.

11. While the data gaps are being filled, currently registered MPs and EPs containing diphenamid as the sole active ingredient may be sold, distributed, formulated and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide and agree to develop additional data, as specified in the Data Appendices of this guidance document, in order to maintain existing registrations.

    Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)).

    Issuance of this standard provides a mechanism for identifying data needs. These data will be evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. Criteria for Registration

To be registered or reregistered under this Standard, manufacturing-use products must contain diphenamid as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this Section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products (MPs) must contain diphenamid as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient which may be present in products.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and MP products containing diphenamid, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing use products containing diphenamid must be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals for Diphenamid lists all registered uses, as well as approved maximum application rates and frequencies.

- Terrestrial food uses on apples, cotton, peaches, black and red raspberries, okra, peanuts, peppers, potatoes, soybeans, strawberries, sweet potatoes, tomatoes, on non-bearing blackberry, blueberry, cherry, lime, orange, and raspberry plants.
- Terrestrial nonfood uses on tobacco, ornamental plants, nursery seed crops, hardwood, tobacco seedbeds, and turf.

D. Required Labeling

All manufacturing-use and end-use diphenamid products must bear appropriate labeling as specified in 40 CFR 162.10, and below. Appendix II contains information on label requirements.

No pesticide products containing diphenamid may be released for shipment by a registrant or producer of that product after July 30, 1988, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide products containing diphenamid may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after July 30, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredient Statement

The ingredient statement for all manufacturing-use products containing diphenamid products must list the active ingredient in the following manner (example):

Diphenamid (N,N-dimethyldiphenylacetamide)..........%";

2. Use Pattern Statements

All manufacturing-use products containing diphenamid must state that they are intended for formulation into end-use products for only the aforementioned use patterns. Labeling must specify sites which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to comply with the data requirements listed in Table A for that use pattern.

3. Precautionary Statements

a. Manufacturing-Use Product Statements

All diphenamid products intended for formulation into end-use products must bear the following statements:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. End-Use Product Statements

The following precautionary statements must appear on the following diphenamid EP labels:

1. (Non-granular)

" Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

2. (Granular)

" Cover, incorporate or collect granules spilled on the soil surface. Do not contaminate water by cleaning of equipment or disposal of wastes."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2].

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Diphenamid as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Diphenamid in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Diphenamid as the sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Diphenamid either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor (PM-25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

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GENERIC DATA REQUIREMENTS FOR DIPHENAMID 97% TECHNICAL[a] (EPA REG. NO. 45639-127)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation[1]	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	All	No	N/A	Yes 2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	N/A	Yes 3/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	N/A	Yes 4/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No	N/A	Yes 5/	12 Months
62-2 - Certification of Ingredient Limits	TGAI	All	No	N/A	Yes 6/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All	No	N/A	Yes 7/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	N/A	Yes 8/	6 Months
63-3 - Physical State	TGAI	All	No	N/A	Yes 8/	6 Months
63-4 - Odor	TGAI	All	No	N/A	Yes 8/	6 Months
63-5 - Melting Point	TGAI	All	No	N/A	Yes 8/	6 Months
63-6 - Boiling Point	TGAI	All	No	N/A	Yes 8/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	N/A	Yes 8/	6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DIPHENAMID, 97% TECHNICAL[a] (EPA REG. NO. 45639-127)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation[1]	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
63-8 - Solubility	TGAI or PAI		No	N/A	Yes 8/	6 Months
63-9 - Vapor Pressure	PAI		No	N/A	Yes 8/	6 Months
63-10 - Dissociation Constant	PAI		No	N/A	Yes 8/	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI		No	N/A	Yes 8/	6 Months
63-12 - pH	TGAI		No	N/A	Yes 8/	6 Months
63-13 - Stability	TGAI		No	N/A	Yes 8/	6 Months
Other Requirement:						
64-1 - Submittal of samples	N/A		No		No 9/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID, 97% TECHNICAL[a] (EPA REG. NO. 45639-127)

§158.120 Product Chemistry (Continued)

[a] The 97% technical serves as a manufacturing-use product.

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that certain data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. The bibliographic citations for old data are not applicable.

2/ The name of each impurity present at >0.1% must be reported.

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a flow chart with chemical equations for each intended reaction, equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used.

4/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and toxicologically significant inerts. Complete validation data (accuracy, precision) must be submitted for each analytical method used. In addition, all nitrosamines must be identified and quantified in six samples; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production.

6/ Upper and lower limits for diphenamid must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for each impurity present at ≥0.1% (w/w), and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA Form 8570-4, Rev. 2-85.

7/ Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ All physicochemical characteristics of the 97%T (EPA Reg. No. 45639-127) (i.e., color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, pH, and stability) or the pure active ingredient (Kow), as required in 49 FR 42890 (Sec. 158-120) and more fully described in the Pesticide Assessment Guideline Subdivision D, must be submitted.

9/ The compound does not require submission of samples at this time.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00093608, 00114601 00093609, 00114613 40200701	Yes 1/2/	18 Months
- Livestock	PAIRA & Plant Metabolites	No	-	Yes 3/4/	18 Months
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	Partially	00035605, 00114570 00043703, 00114586 00106180, 00114590	Yes 5/6/	15 Months
- Animal Residues	TGAI	No	-	Yes 5/6/	15 Months
171-4 - Storage Stability Data	PAI	Partially	00035601, 00093614 00035602, 00114577 00035603, 00114585	Yes 7/8/	15 Months
171-4 - Magnitude of the Residue - Residue Studies					
a. Root & Tuber Vegetables 9/					
° Potatoes					
-- Crop Field Trials	TEP	Partially	00114577, 00114601 00114588,	Yes 10/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 11/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue - Residue Studies					
° Sweet Potatoes					
-- Crop Field Trials	TEP	Yes	00035596, 00073539 00035649	No	
b. Legume Vegetables 12/					
° Soybeans					
-- Crop Field Trials	TEP	Yes	00035648, 00114566	No	
-- Processed Food/Feed	EP	No	-	Yes 13/	24 Months
c. Fruiting Vegetables (Except Cucurbits)					
° Peppers					
-- Crop Field Trials	TEP	Partially	00114585	Yes 14/	18 Months
° Tomatoes					
-- Crop Field Trials	TEP	Yes	00105710, 00114601 00106180, 00138452 00114570	No	
-- Processed Food/Feed	EP	No	-	Yes 15/	24 Months
d. Pome Fruits 16/					
° Apples					
-- Crop Field Trials	TEP	Partially	00035607, 00035612	Yes 17/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 18/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue - Residue Studies					
e. Stone Fruits 19/					
° Peaches					
-- Crop Field Trials	TEP	Yes	00035610,	No	
f. Small Fruits & Berries 20/					
° Raspberries					
-- Crop Field Trials	TEP	Partially	00029335, 00114602	Yes 21/	18 Months
° Strawberries					
-- Crop Field Trials	TEP	Yes	00093614, 00114594	No	
g. Miscellaneous Commodities					
° Cottonseed					
-- Crop Field Trials	TEP	Yes	00035608	No	
-- Processed Food/Feed	EP	No	-	Yes 22/	24 Months
° Okra					
-- Crop Field Trials	TEP	Yes	00035609, 00114600	No	
° Peanuts					
-- Crop Field Trials	TEP	Yes	00026700, 00035611 00031791, 00035647 00035595,	No	
-- Processed Food/Feed	EP	No	-	Yes 23/	24 Months
° Tobacco					
-- Crop Field Trials	TEP	No	-	Yes 24/	18 Months
-- Processed	EP	No	-	Yes 25/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue - Residue Studies					
d. Meat/Milk/ Poultry/Eggs	TGAI or Plant Metabolites	Partially	00114586	Reserved 26/	
- Potable Water	TEP	No		No 27/	
- Fish	TEP	No		No 27/	
- Irrigated Crops	TEP	No		No 27/	
- Food Handling	TEP	No		No 27/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

§158.125 Residue Chemistry - Continued

1/ Data must be submitted depicting the uptake, distribution, and metabolism of ring-labeled [^{14}C]diphenamid (or carbon labeled [^{14}C]diphenamid) in potatoes following preemergence or layby applications, and in tomatoes following broadcast or band treatment one month after direct seeding or transplanting at a rate sufficiently high to permit complete ^{14}C-residue identification. Plants must be harvested for residue characterization at regular intervals until maturity.

2/ Representative samples from the requested plant metabolism studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

3/ Metabolism studies must be submitted utilizing ruminants and poultry. Animals must be dosed for three days with ring-labeled [^{14}C]diphenamid at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrified within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

4/ Representative samples from the requested animal metabolism studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

5/ Residues of MDA in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from National Technical Information Service under Order No. PB 203734/AS.

6/ Additional methods, validation data, and residue data (for representative commodities) may be required if the metabolism studies requested in footnotes 4 and 6 indicate that additional metabolites may constitute residues of toxicological concern in plants or animals.

7/ The storage intervals and conditions of storage of samples used to support all established tolerances for residues of diphenamid including its desmethyl metabolite must be submitted. These data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified. On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

8/ All residue data requested in this Standard must be accompanied by data regarding storage intervals and conditions of sample storage. These data must be accompanied by fortification recovery data depicting the stability of diphenamid residues of concern in appropriate sample substances under the conditions for the time intervals specified.

§158.125 Residue Chemistry - Continued

9/ If the registrant seeks a crop group tolerance, tolerances and use directions must be proposed, and supporting residue data submitted for additional representative group members (carrot, radish, and sugar beet).

10/ Data must be submitted depicting residues of concern in or on potatoes harvested 50 days following preemergence broadcast application (in at least 30 gal water/A), and, in separate tests, layby application of the 50 or 90% WP formulation at 6 lb ai/A. Tests must be conducted in ID(24%), ME(6%), and WA(16%), states which are representative of the major U.S. potato production regions (Agricultural Statistics, 1985, p. 164).

11/ Data must be submitted depicting diphenamid residues of concern in or on granules, dried peels and dried chips processed from potatoes bearing measurable weathered residues. It may be necessary to use exaggerated rates to achieve such residues. If residues are found to concentrate in any processed product, appropriate food/feed additive tolerances must be proposed.

12/ If the registrant seeks a crop group tolerance, use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members beans (succulent and dry) and peas.

13/ Data must be submitted depicting diphenamid residues of concern in hulls, crude oil, refined oil, meal, and soap stock processed from soybeans bearing measurable, weathered residues. In may be necessary to use exaggerated rates to obtain such residues. If residues are found to concentrate upon processing, then appropriate food/feed additive tolerances must be proposed.

14/ If the registrant seeks a crop group tolerance, additional data are required depicting diphenamid residues of concern in or on peppers treated within one month following direct seeding or transplanting with a single broadcast application of a WP or FlC (4 lb/gal) formulation at 5 lb ai/A. Tests must be conducted in CA(18%), FL(23%), and TX(16%) which represent the major U.S. sweet pepper growing regions (1982 Census of Agriculture, pp. 349-350).

15/ Data must be submitted depicting diphenamid residues of concern in or on catsup, juice, puree, and dry pomace processed from tomatoes bearing measurable weathered residues. Exaggerated application rates may be necessary to achieve such residue levels. If residues are found to concentrate in any processed product, appropriate food/feed additive tolerances must be proposed.

16/ If the registrant desires a crop group tolerance, use directions must be proposed, and appropriate supporting residue data submitted for the representative group member pears.

17/ Data must be submitted depicting diphenamid residues of concern in or on apples harvested 90 days following one directed spray soil application of a WP formulation at 6 lb ai/A. Tests must be conducted in MI(9%), NY(12%), WA(36%), and VA(6%) (state percent of total U.S. production given parenthetically; data from Agricultural Statistics, 1985, p. 196).

§158.125 Residue Chemistry - Continued

18/ Data must be submitted depicting diphenamid residues of concern in apple juice and dry pomace processed from apples bearing measurable weathered residues (exaggerated application rates may be necessary to achieve such residues). If residues are found to concentrate in either commodity, then appropriate food/feed additive tolerances must be proposed.

19/ If the registrant seeks a crop group tolerance, use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group members cherries and plums.

20/ If the registrant seeks a crop group tolerance, use directions must be proposed, and appropriate supporting residue data submitted for additional representative group members (blueberries, cranberries, and grapes).

21/ Data depicting diphenamid residues of concern in or on raspberries harvested 60 days following one directed spray soil application of a WP formulation at 6 lb ai/A must be submitted. Field trials must be conducted in MI(3%) and WA(44%) (state percentages of U.S. raspberry acreage appear parenthetically) (1982 Census of Agriculture, Vol. 1, Pt. 51, p. 372).

22/ Data must be submitted depicting diphenamid residues of concern in hulls, meal, crude oil, refined oil, and soapstock processed from cottonseed bearing measurable, weathered residues. It may be necessary to use exaggerated rates to obtain such residues. If residues are found to concentrate upon processing then appropriate food/feed additive tolerances must be proposed.

23/ Data must be submitted depicting diphenamid residues of concern in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable, weathered residues (exaggerated rates may be necessary to achieve such residues). If residues concentrate in these processed commodities, appropriate food/feed additive tolerances must be proposed.

24/ Data must be submitted depicting diphenamid residues of concern in or on green, freshly harvested tobacco receiving the following full-season treatment schedules in separate tests: one broadcast soil application 7 days after transplanting of a WP formulation at 6 lb ai/A followed by one soil band application at layby after the last cultivation of a WP formulation at 2 lb ai/A; and (ii) the same applications except at 2 and 6 lb ai/A, respectively. Applications must be made by ground equipment.

25/ If residues in freshly harvested green tobacco exceed 0.1 ppm, data depicting residues in or on dried or cured tobacco will be required. If residues in or on dried or cured tobacco exceed 0.1 ppm, pyrolysis products derived from the active ingredient must be characterized and the level of residue in smoke must be quantified. (Ring-labeled [^{14}C]diphenamid must be used for identification of pyrolysis products.)

26/ The nature of the residue in animals is not adequately understood and outstanding data gaps exist for many processed feed items. Upon receipt of the data requested in the sections "Nature of the Residue in Animals" and "Magnitude of the Residue in Animals", the established tolerances will be assessed, and the adequacy of the available data regarding the magnitude of residues will be determined with consideration for any additional residues of toxicological concern.

27/ The Guidelines and use patterns indicate that these data are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00157344	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A	No	-	Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Reserved 1/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	-	Yes	July 1987 2/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes	July 1987 2/
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	No	-	No 3/	
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	No		No 5/	
MOBILITY STUDIES:						
163-1 - Leaching & Adsorption/ Desorption	TGAI or PAIRA	A,B	No	-	Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No	-	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Reserved 4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	A	No		No 5/	
164-3 - Forestry	TEP	A	No		No 3/	
164-4 - Combination and Tank Mixes	- -	A,B	No		No 6/	
164-5 - Soil, Long-term	TEP	A	No		Reserved 7/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved 8/	
165-3 - Irrigated Crops	TEP	N/A	No		No 5/	
165-4 - In Fish	TGAI or PAIRA	A	No		Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	N/A	No		No 5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		Reserved 9/	
132-1 - Soil Dissipation	TEP	A	No		Reserved 9/	
133-3 - Dermal Exposure	TEP	A,B	No		Reserved 9/	
133-4 - Inhalation Exposure	TEP	A,B	No		Reserved 9/	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No		Reserved 9/	
201-1 - Drift Field Evaluation	TEP	A	No		Reserved 9/	

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TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

§158.130 Environmental Fate - Continued

1/ Photodegradation test in air is reserved pending results of the laboratory volatility studies.

2/ The registrant requested on 2/11/87 an extension of time from March 1987 to July 1987 to complete the following soil metabolism tests: 162-1 and 162-2. The Agency has granted the extension of time for these soil metabolism tests.

3/ The Agency has waived the data requirements for (a) anaerobic aquatic study [162-3] and (b) forestry dissipation study [164-3] which were required in the Ground Water Data Call-In Notice of 6/26/84. This decision has taken into consideration that the registrant has revised all forestry uses to ornamental uses for diphenamid products.

4/ Field volatility study is reserved pending results of the laboratory studies.

5/ The Guidelines and use patterns indicate that these data are not required.

6/ The data requirements for combination and tank mixes are not being imposed in this Standard.

7/ Soil long term study is reserved pending results of acceptable aerobic soil metabolism and field dissipation studies.

8/ Rotational crop field study is reserved pending results of an acceptable confined rotational crop study.

9/ Reentry and spray drift data may be required if the results of the toxicity tests being required under this Standard indicate that a significant chronic toxicity hazard may exist.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity	TGAI	A,	Yes	00114560	No	
81-2 - Acute Dermal Toxicity	TGAI	A,	Yes	00114575	No	
81-3 - Acute Inhalation Toxicity	TGAI	A,	No	-	Yes	9 Months
81-4 - Primary Eye Irritation	TGAI	A,	Yes	00077881	No	
81-5 - Primary Dermal	TGAI	A,	No	-	Yes	9 Months
81-6 - Dermal Sensitization	TGAI	A,	No	-	Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,	No		No 1/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding - Rodent Nonrodent (dog)	TGAI	A,	No		No 4/	
82-2 - 21-Day Dermal	TGAI	A,	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SUBCHRONIC TESTING:						
82-3 - 90-Day Dermal	TGAI	A,	No		No 2/	
82-4 - 90-Day Inhalation	TGAI	A,	No		Reserved 5/	
82-5 - 90-Day Neurotoxicity-Hen	TGAI	A,	No		No 1/	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - Rodent (rat)	TGAI	A,	No		Yes	50 Months
Nonrodent (dog)	TGAI	A,	Yes	00076382	No	
83-2 - Oncogenicity - Rat	TGAI	A,	No	-	Yes	50 Months
Mouse	TGAI	A,	No	-	Yes	June 1988
83-3 - Teratogenicity - Rat	TGAI	A,	No	-	Yes	15 Months
Rabbit	TGAI	A,	No	-	Yes	15 Months
83-4 - Reproduction - 2-generation	TGAI	A,	Yes	00076383	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,	No	-	Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,	No	-	Yes	12 Months
84-2 - Other Genotoxic Effects	TGAI	A,	No	-	Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,	Partially	00077893, 00093606	Yes	24 Months
85-2 - Domestic Animal Safety	Choice	A,	No		No 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

§158.135 Toxicology - Continued

1/ Because diphenamid is not structurally related to the known family of neurotoxins, organophosphates, this neurotoxicity study is not required.

2/ This study is not needed because the existing acceptable end-uses should not result in repeated human skin contact for extended periods.

3/ Use patterns in conjunction with the Guidelines indicate that these data are not required.

4/ This study is not necessary since an adequate chronic feeding dog study is available.

5/ A subchronic inhalation study is required for use on tobacco if residues occur in dried tobacco.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	A,B	No	-	Yes	9 Months
71-2 - Avian Dietary LC_{50}						
a. Waterfowl	TGAI	A,B	No	-	Yes	9 Months
b. Upland game bird	TGAI	A,B	No	-	Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B	No		No 1/	
71-4 - Avian Reproduction						
a. Waterfowl	TGAI	A,B	No		No 2/	
b. Upland game bird	TGAI	A,B	No		No 2/	
71-5 - Simulated Field Testing - Mammals, and - Birds	TEP	A,B	No		No 1/ 2/	
Actual Field Testing - Mammals, and - Birds	TEP	A,B	No		No 1/ 2/	
AQUATIC ORGANISM TESTING						
72-1 - Acute Toxicity, Freshwater Fish						
a. Warmwater	TGAI	A,B	No	-	Yes	9 Months
b. Coldwater	TGAI	A,B	No	-	Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AQUATIC ORGANISM TESTING						
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B	Yes	00138963	No	
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B	No		No 3/	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B	No		No 3/	
72-5 - Fish full life-cyle	TGAI	A,B	No		No 3/	
72-6 - Aquatic Organism Accumulation	TGAI, PAI, Degradation Product	A,B	No		No 3/	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B	No		No 3/	
- Actual Field Testing - Aquatic Organisms						

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.150 Plant Protection						
121-1 - Target Area Phytotoxicity	TGAI	A,B	No		No 4/	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B	No		No 4/	
122-1 - Vegetative Vigor	TGAI	A,B	No		No 4/	
122-2 - Aquatic Plant Growth	TGAI	A,B	No		Yes 5/	9 Months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B	No		No 4/	
123-1 - Vegetative Vigor	TGAI	A,B	No		No 4/	
123-2 - Aquatic Plant Growth	TGAI	A,B	No		No 4/	
TIER III						
124-1 - Terrestrial Field	TGAI	A,B	No		No 4/	
124-2 - Aquatic Field	TGAI	A,B	No		No 4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Surrogate data indicate that diphenamid is low in toxicity to mammals, therefore the study is not required.

2/ Data on a formulated product indicate that diphenamid is very low in toxicity to waterfowl and upland gamebirds, therefore, the studies are not required.

3/ Data on formulated products and surrogate data indicate that these studies are not required.

4/ Phytotoxicity testing can be required on a case-by-case basis to support, among others, end-use products that may pose hazard to endangered or threatened plant species.

5/ Required for large acreage herbicide use with the potential for runoff into aquatic systems.

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A	Yes	00018842	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No		No 1/	
141-4 - Honey bee subacute feeding study	(Reserved) 2/					
141-5 - Field testing for pollinators	TEP	A	No		No 1/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved) 3/					
142-1 - Aquatic insect life-cycle study	(Reserved) 3/					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 3/					
NONTARGET INSECT TESTING						
143-1 thru 143-3 - Predators and Parasites	(Reserved) 3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR DIPHENAMID

1/ Data from the acute contact study show low toxicity to honey bees. Therefore, no further testing is required.

2/ Data requirements are reserved pending development of test methodology.

3/ Data requirements are reserved pending an Agency decision as to whether the data requirement should be established.

TABLE B-1

PRODUCT SPECIFIC DATA REQUIREMENTS FOR DIPHENAMID 95% FI^a (EPA REG.NO. 45639-120)
PRODUCT SPECIFIC DATA REQUIREMENTS FOR DIPHENAMID 90% FI^b (EPA REG.NO. 45639-108)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation[1]	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	-	Yes 2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	-	Yes 3/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	-	Yes 4/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	All	No	N/A	Yes 5/	12 Months
62-2 - Certification of Ingredient Limits	MP	All	No	N/A	Yes 6/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No	-	Yes 7/	12 Months
Other Requirements:						
64-1 - Submittal of Samples	N/A		No	N/A	No 8/	

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TABLE B-1

PRODUCT SPECIFIC DATA REQUIREMENTS FOR DIPHENAMID 95% FI[a] & 90% FI[b] (EPA REG.NOS. 45639-108 and 120)

§158.120 Product Chemistry (Continued)

a The 95% formulation intermediate (FI) serves as a manufacturing-use product.
b The 90% formulation intermediate (FI) serves as a manufacturing-use product.

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that certain data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. The bibliographic citations for old data are not applicable.

2/ The chemical name and CAS Registry no. of each intentionally added inert must be submitted, along with the identity (e.g., EPA Reg. No.).

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a flow chart with chemical equations for each intended reaction, equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer or supplier of each beginning material must be provided along with information regarding the properties of each beginning material used.

4/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and toxicologically significant inerts. Complete validation data (accuracy, precision) must be submitted for each analytical method used. In addition, all nitrosamines must be identified and quantified in six samples; two samples each must be analyzed shortly after production, 3 months after production, and 6 months after production.

6/ Upper and lower limits for diphenamid must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper and lower limits for each intentionally added inert must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for each impurity present at ≥0.1% (w/w), and for each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA Form 8570-4, Rev. 2-85.

7/ Analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity and intentionally added inert for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ The compound does not require submission of samples at this time.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIPHENAMID

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity	TGAI	A,	Yes	00114560	No	
81-2 - Acute Dermal Toxicity	TGAI	A,	Yes	00114575	No	
81-3 - Acute Inhalation Toxicity	TGAI	A,	No	-	Yes	9 Months
81-4 - Primary Eye Irritation	TGAI	A,	Yes	00077881	No	
81-5 - Primary Dermal	TGAI	A,	No	-	Yes	9 Months
81-6 - Dermal Sensitization	TGAI	A,	No	-	Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,	No		No 1/	

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1/ Diphenamid is not an organophosphate and available data do not indicate a neurotoxicological problem.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.
[40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container.
[40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

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DIPHENAMID*

TYPE PESTICIDE: Herbicide

FORMULATIONS:

Tech	(97%)
FI	(90%, 95%)
G	(1.42%, 2.3%, 2.65%, 3.44%, 3.5%, 5.3%)
WP	(50%, 80%, 90%)
EC	(18.3%)
FlC	(1.39 lb/gal or 15.4% a.i., 4 lb/gal or 42.5% a.i.)

GENERAL WARNINGS AND LIMITATIONS: A selective preemergence herbicide used to control broadleaf weeds and grasses in agricultural and noncrop areas. A light rainfall or irrigation following application will improve weed control. Incorporation may be necessary under dry soil conditions. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not apply to lakes, ponds, or streams. Cover, incorporate or collect granules spilled on the soil surface. Do not contaminate water sources by cleaning of equipment or disposal of wastes. Crops other than those registered for this product should not be planted in treated soil for 6 months after the last treatment. Do not use product in direct combination with fertilizers, insecticides, fungicides, or with other herbicides except as specifically recommended.

Livestock Tolerances:

Cattle, fat	0.05 (N) ppm
Cattle, meat	0.05 (N) ppm
Cattle, mbyp	0.05 (N) ppm
Goats, fat	0.05 (N) ppm
Goats, meat	0.05 (N) ppm
Goats, mbyp	0.05 (N) ppm
Hogs, fat	0.05 (N) ppm
Hogs, meat	0.05 (N) ppm
Hogs, mbyp	0.05 (N) ppm
Horses, fat	0.05 (N) ppm
Horses, meat	0.05 (N) ppm
Horses, mbyp	0.05 (N) ppm
Milk	0.01 (N) ppm
Sheep, fat	0.05 (N) ppm
Sheep, meat	0.05 (N) ppm
Sheep, mbyp	0.05 (N) ppm

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits seed germination or early seedling growth and root elongation by affecting the uptake of inorganic ions and influencing the distribution of calcium.

*N,N-dimethyl-2,2-diphenylacetamide

DIPHENAMID

BROADLEAF WEEDS CONTROLLED:

PBFBABB	Brassbuttons
PADABBA	Carpetweed
PAZAAAC	Chickweed
PAZAOBB	Common chickweed
PBFAEBA	Common ragweed
PAZAXBA	Corn spurry
PBFBPAA	Cudweed
PDNAFAA	Eveningprimrose
PBKAWBA	Field pepperweed
PBZABAA	Filaree
PEMAEBB	Florida pusley
PBFCXAA	Groundsel
PAZAKBA	Knawel
PEAAGAC	Knotweed
PBDAEAB	Lambsquarters
PDAAHAA	Mallow
PAZADBC	Mouseear chickweed
PDPABAA	Oxalis
PAZAIAA	Pearlwort
PAAAABI	Pigweed
PAAAABP	Purslane
PEAAHBB	Red sorrel
PAFACBI	Redroot pigweed
PBKAHBA	Shepherdspurse
PEAAGAD	Smartweed
PAFACBJ	Spiny amaranth
PBVAGBK	Spotted spurge
PZAAAGJ	Spurweed
PAZACBA	Thymeleaf sandwort
PCQBYBJ	White clover

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCACKBA	Annual bluegrass
PCAAAAB	Annual grasses
PBMADBO	Annual sedge
PCABHBB	Barnyardgrass
PCAADAA	Bentgrass
PCAAZBA	Bermudagrass
PCACKAA	Bluegrass
PCAATBK	Cheat
PCABMAC	Coarse fescue
PCABRBA	Common velvetgrass
PCABFAA	Crabgrass
PCABCBA	Crowfootgrass
PCACEBD	Fall panicum
PCACUAA	Foxtail
PCABSBC	Foxtail barley
PCACUBA	Giant foxtail
PCABIBA	Goosegrass
PCACWBC	Johnsongrass (from seed)

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

PCACFBD	Knotgrass
PCABFBF	Large crabgrass
PZAAAAX	Perennial bluegrass
PCAADBA	Redtop
PCABZAA	Ryegrass
PCAAWAA	Sandbur
PCABFBD	Smooth crabgrass
PCABKBC	Stinkgrass
PCAAOBB	Wild oats
PCACEBC	Witchgrass
PCACUBD	Yellow foxtail

	Site, Dosage and Formulation (lb a.i. /A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
/04001AA /05004AA	Apple Peach	0.1 (N) ppm 90 day preharvest interval. Do not allow livestock to graze treated areas. General Information: Do not apply when fruit is on the tree. For peaches, do not use on coarse textured soils.
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Directed spray to soil around established trees. Apply following a clean cultivation and incorporate into the soil. Apply in at least 30 gallons of water per acre.
/01002DA /01009DA /05002DA /02005DA /02006DA /01006DA	Blackberry (non-bearing) Blueberry (non-bearing) Cherry (non-bearing) Lime (non-bearing) Orange (non-bearing) Raspberry (non-bearing)	Tolerance not located. 12 month preharvest interval for blackberry, cherry, lime, and orange. General Information: May be used on new plantings and container stock after plants are established.
	4-6 (50% WP) (4 lb/gal FlC)	Broadcast application to seedbeds. Apply within 2 days after seeding and mulching. Apply 0.5 to 0.75 inch of water by overhead sprinkler irrigation after treatment.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Blackberry (non-bearing) cluster (continued)	
	4-6 (50%, 90% WP)	Broadcast. Apply in the fall or spring before weeds emerge. Apply in 10 gallons of water.
/01019AA /01018AA	Black Raspberry Red Raspberry	1.0 ppm 60 day preharvest interval. 12 month preharvest interval for red raspberry. Do not use more than 6 pounds active ingredient during a growing season.
	2-6 (50%, 90% WP) (4 lb/gal FlC)	Directed spray to the soil. Apply after planting but before weeds germinate. Apply prior to weed emergence in established plantings or immediately following a cultivation.
/23005AA	Cotton	0.2 ppm (cotton, forage) 0.1 (N) ppm (cottonseed)
	3-4 (50%, 90% WP) (4 lb/gal FlC)	Broadcast application at planting. Apply in at least 30 gallons of water per acre.
/15015AA	Okra	0.1 (N) ppm
	3-5 (50%, 90% WP) (4 lb/gal FlC)	Broadcast application at planting. Use the lower dosage on light mineral soils and the higher dosage on medium/fine mineral soils.
	Peach	See Apple cluster.
/23007AA	Peanuts	2.0 ppm (peanuts, forage, hay) 0.5 ppm (peanut hulls) 0.1 (N) ppm (peanuts)
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Broadcast application at planting. Apply in 30 to 50 gallons of water. OR
	2-3 (50%, 90% WP) (4 lb/gal FlC)	Cracking stage application or within 7 days after cracking. Tank mix with dinoseb. OR

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Peanuts (continued)	
	2 (50%, 90% WP) (4 lb/gal FlC)	Layby application following last cultivation. Will not control established weeds. Do not use if more than 2 pounds active ingredient per acre were applied at planting or cracking stages.
//11003AA	Peppers	0.1 (N) ppm (fruiting vegetables) Do not graze treated areas. General Information: Before treatment, work all weed growth into soil.
	3-5 (50%, 80%, 90% WP) (4 lb/gal FlC)	Direct seeding treatment. apply in 20 to 50 gallons of water per acre. OR Broadcast application to transplants or within 1 month after transplanting.
	[SLN] 5 (50%, 90% WP)	SLN - Use limited to CA. Preplant application. Apply by air once per season.
/14013AA	Potato	1.0 ppm 50 day preharvest interval. General Information: Any tillage operation such as dragging-off, hilling, etc., that brings untreated soil to the surface will result in poor weed control. However, shallow cultivation (0.5 to 2 inches) after application will not reduce effectiveness.
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Preemergence. Broadcast. Apply in at least 30 gallons of water per acre. OR Layby application. Directed spray to base of plants.
	[SLN] 6 (50%, 90% WP)	SLN - Use limited to CA. Preplant application. Apply by air once per season.
	Red Raspberry	See Black Raspberry cluster.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/28023AA	Soybeans	0.5 ppm (soybean, forage, hay) 0.1 (N) ppm (soybean) Do not plant food crops other than soybeans within 6 months after treatment.
	2-5 (50%, 90% WP) (4 lb/gal FlC)	At planting. Broadcast.
	2-3 (4 lb/gal FlC)	At planting. Broadcast or band. Tank mix with linuron or chlorpropham.
/01016DA	Strawberry	1.0 ppm 60 day preharvest interval. General Information: Do not use on the herbicide sensitive variety Shasta. A temporary delay in rooting of daughter plants may occur but will not affect yield.
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Posttransplant application. Apply 2 to 6 weeks after planting but before new foliage has appeared. Use the lower dosage on light mineral soils and the higher dosage on medium/fine mineral soils. Apply in 30 to 50 gallons of water.
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Dormant application to established plantings. May be applied to semi-dormant plantings or after bed renovation. Additional applications may be made at intervals of 6 months or more.
/14018AA	Sweet Potato	0.1 (N) ppm
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Postplant application to soil after covering sweet potatoes. Broadcast or band. May be tank mixed with chloramben or oryzalin for preemergent weed treatment.
	2-6 (50%, 90% WP) (4 lb/gal FlC)	Posttransplant. Broadcast or band. May be tank mixed with chloramben or oryzalin for preemergent weed treatment.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/11005AA	Tomato	0.1 (N) ppm (vegetable, fruiting) General Information: Following initial watering, beds should be kept at the optimum moisture level for seed germination and emergence. Allowing the seedbed to dry out reduces the level of herbicide effectiveness as well as the stand and vigor of the tomato plants. Do not use on soils with over 10 percent organic matter or on soils with a salt problem.
	4-6 (50%, 80%, 90% WP) (4 lb/gal FlC)	Broadcast or band treatment. Apply 1 week before to 1 month after direct seeding or transplanting.
	2-4 (50%, 80%, 90% WP) (4 lb/gal FlC)	Broadcast or band treatment. Apply 1 week before to 1 month after direct seeding or transplanting. May be tank mixed with trifluralin, pebulate, or napropamide. Do not tank mix with trifluralin or pebulate for use on direct seeded tomatoes except in CA.
	4-6 (50%, 90% WP) (4 lb/gal FlC)	Use limited to CA. Preplant application to fields to be planted in with direct seeded tomatoes. Broadcast. Apply to prepared beds and incorporate into the soil (1 to 2 inches) with a power driven tiller. Do not apply earlier than 14 days before seeding. Immediately following incorporation and seeding, the beds should be thoroughly wet by furrow irrigation. OR
	4-6 (90% WP) (4 lb/gal FlC)	Use limited to CA. Preplant application to fields to be planted with direct seeded tomatoes. Broadcast with disk incorporation. Apply in at least 30 gallons of water per acre. Following application the field should be double-disked with the second disk at right angles to the first to uniformly incorporate into the soil to a depth of 3 to 4 inches. Following bedding and seeding the beds should be thoroughly wet using furrow irrigation.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Tomato (continued)	
4-6 (90% WP) (4 lb/gal FlC)	Use limited to CA. Preplant application. Broadcast to direct-seeded tomatoes. Apply in 30 to 50 gallons of water per acre. Incorporate into the soil to a depth of 2 to 3 inches. Do not use the trifluralin tank mix on soils containing more than 5 percent organic matter, or soils with a salt problem. Tank mix with trifluralin or pebulate.
6 (90% WP) (4 lb/gal FlC)	Use limited to CA. Broadcast application to fields prepared in the fall for early spring planting of direct seeded tomatoes. Apply prior to the start of the winter rainy season (October or November). Do not incorporate into the soil mechanically. Tomatoes may be planted through March 1 in the treated fields. Do not use a fall application on fields to be planted after March 1.
4-6 (50%, 90% WP) (4 lb/gal FlC)	Use limited to CA. Broadcast application at planting or immediately after without soil incorporation. After application, 1 to 2 inches of water should be applied by sprinkler irrigation.
[SLN] 4-6 (50%, 90% WP)	SLN - Use limited to CA. Preplant application. Apply once per season in at least 30 gallons of water per acre. Tank mix with napropamide.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL NONFOOD CROP	
	(Agricultural Crops)	
/26003AA	Tobacco	Do not graze treated areas. General Information: Rainfall or overhead irrigation within a week of treatment will enhance herbicidal effectiveness. When applied more than 2 days after transplanting tillage is required before or at time of treatment to destroy germinating weed seeds. Small grain cover crops planted in the fall following treatment may be injured. When these crops are to be grown, a band treatment to tobacco is recommended. Do not use more than a total of 8 pounds active ingredient per acre per season.
	4-6 (50%, 80%, 90% WP) (4 lb/gal FlC)	Broadcast application to seedbeds. Apply at seeding to control white clover. Use the lower dosage on coarse soils and the higher dosage on medium/fine soils. May be tank mixed with metalaxyl.
		Broadcast. Apply from 0 to 7 days before transplanting or up to 7 days after transplanting. Incorporate into the top 2 inches of soil. Apply in 20 to 40 gallons of water per acre. May be tank mixed with trichlorfon. OR Broadcast or band treatment at layby following last cultivation, usually 4 to 6 weeks after transplanting. If application was used before or after transplanting apply 2 to 4 pounds active ingredient per acre. May be tank mixed with pebulate.
	2-4 (4 lb/gal FlC)	Pretransplant. Apply up to 7 days before transplanting. Tank mix with trichlorfon, isopropalin, pendimethalin, or pebulate.
	2-4 (50%, 80%, 90% WP)	Band treatment at layby. Apply to row middles following last cultivation. Do not spray tobacco leaves as injury may occur. Tank mix with oryzalin.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Tobacco (continued)	
4-6 (50%, 80%, 90% WP)	Band treatment at layby. Apply to row middles following last cultivation. Do not spray tobacco leaves as injury may occur. Tank mix with metalaxyl.
[SLN] 4-6 (50%, 90% WP)	SLN - Use limited to NC, SC and VA. Broadcast. Apply before transplanting, after transplanting, or at layby to suppress common ragweed. Use the lower dosage on coarse mineral soils and the higher dosage on medium/fine mineral soils.

(Ornamental Plants and Forest Trees)

/31001DA	African Daisy
/31017DA	Alyssum
/31026DA	Aster
/31028DA	Baby's Breath
/31034DA	Begonia
/31045DA	Butterfly Orchid
/31051DA	California Poppy
/31065DA	Chrysanthemum
/31077DA	Cosmos
/31084DA	Dahlias
/31100DA	Feverfew
/31108DA	Geranium
/31413DA	Heliotrope
/31287DA	Indian Laurel
/31129DA	Larkspur
/31411DA	Lily-of-the-Nile
/31133DA	Lobelia
/31412DA	Loosestrife
/31137DA	Marigold
/31151DA	Peonies
/31154DA	Petunias
/31155DA	Philodendron
/31156DA	Phlox
/31171DA	Salvia
/31180DA	Shasta Daisy
/31184DA	Snapdragon
/31188DA	Stocks
/31198DA	Sweet William
/31206DA	Verbena
/31410DA	Yellow Foxglove
/31213DA	Zinnia

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	African Daisy cluster (continued)	
	0.5-1.25 lb a.i./ 5,000 sq.ft (50%, 90% WP) (1.39, 4 lb/gal FlC)	Broadcast application. Apply at transplanting in the fall or spring before weeds emerge. Apply the lower rates to coarse soils and the higher doses to medium/fine soils. Repeat application in 6 months. May be formulated with carbaryl.
	[MAI] 1.0 lb a.i./5,000 sq.ft (2.3% G)	
/35324DA	Aleppo Pine	
/35094DA	Apple (ornamental)	General Information: Marginal leaf chlorosis may develop on oleander. May be used on new plantings and containerized stock after plants are established.
/35021DA	Arborvitae	
/35022DA	Ash	
/34022DA	Azalea	
/35025DA	Baldcypress	
/34025DA	Barberry	
/34028DA	Beauty Bush	
/35027DA	Beech	
/35028DA	Birch	
/35030DA	Black Locust	
/35031DA	Black Walnut	
/35032DA	Blackgum	
/34262DA	Bottlebush	
/34031DA	Boxwood	
/35359DA	California Fan Palm	
/34035DA	California Privet	
/35460DA	Cajeput Tree	
/34036DA	Camellia	
/35273DA	Carob	
/35384DA	Carolina Cherry Laurel	
/34158DA	Ceanothus	
/34040DA	Cherry Laurel	
/35039DA	Chestnut	
/35235DA	Chinese Chestnut	
/34045DA	Cotoneaster	
/35133DA	Cottonwood	
/35056DA	Crabapple (ornamental)	
/34984DA	Cream Carpet	
/34360DA	Crown-of-Thorns	
/35474DA	Cupaniopsis anacardiopsis	
/34050DA	Deutzia	
/35043DA	Dogwood	
/34051DA	Elaeagnus	
/35050DA	Eucalyptus	

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Aleppo Pine cluster (continued)	
/34053DA	Euonymus	
/35360DA	Fern Podocarpus	
/34056DA	Fetter-Bush	
/34057DA	Ficus	
/34058DA	Firethorn	
/35052DA	Flowering Almond	
/34060DA	Flowering Currant	
/34062DA	Forsythia	
/34246DA	Harlands Boxwood	
/35362DA	Hawaiian Tree Fern	
/34067DA	Heath	
/34100DA	Heavenly Bamboo	
/35068DA	Hemlock	
/34070DA	Holly	
/35070DA	Honeylocust	
/34072DA	Honeysuckle	
/34073DA	Hydrangea	
/34075DA	India Hawthorn	
/35458DA	Jacaranda acutifolia	
/35185DA	Japanese Black Pine	
/34080DA	Japanese Holly	
/34190DA	Japanese Snowball	
/35072DA	Japanese Yew	
/35073DA	Juniper	
/34215DA	Laurel	
/34088DA	Ligustrum	
/34089DA	Lilac	
/35192DA	London Plane	
/34090DA	Mahonia	
/35083DA	Maple	
/34416DA	Mirror Plant	
/34094DA	Mock Orange	
/35196DA	Monterey Pine	
/35361DA	Moreton Bay Fig	
/34097DA	Mountain-Laurel	
/35086DA	Mugho Pine	
/34098DA	Multiflora Rose	
/35089DA	Norway Maple	
/35093DA	Oak	
/34102DA	Oleander	
/35367DA	Olive (ornamental)	
/35254DA	Oriental Arborvitae	
/35310DA	Ornamental Evergreen Pear	
/35058DA	Peach (ornamental)	
/35059DA	Pear (ornamental)	
/35353DA	Pecan (ornamental)	
/35255DA	Pin Oak	

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Aleppo Pine cluster (continued)	
/35098DA	Pine	
/34112DA	Pineapple Guava	
/34428DA	Pink Indian Hawthorn	
/34113DA	Pittosporum	
/35060DA	Plum (ornamental)	
/35204DA	Red Maple	
/35105DA	Red Oak	
/35103DA	Redbud	
/35104DA	Redcedar	
/34555DA	Rhododendron	
/34120DA	Rose	
/34208DA	Sakaki	
/34122DA	Sandankwa Viburnum	
/34124DA	Sasanqua Camellia	
/35206DA	Scarlet Oak	
/34068DA	Scotch Heather	
/35209DA	Shore Juniper	
/34209DA	Shrub-Althea	
/35211DA	Silver Maple	
/35364DA	Spineless Yucca	
/34130DA	Spirea	
/34121DA	St. Johnswort	
/34132DA	Star Jasmine	
/35117DA	Sugar Maple	
/35118DA	Sweetgum	
/35119DA	Sycamore	
/34219DA	Tobira	
/35120DA	Tuliptree	
/34137DA	Viburnum	
/34415DA	Victoria-Box	
/34140DA	Weigela	
/34224DA	Weigela (bristol ruby)	
/35227DA	White Ash	
/35248DA	White Birch	
/35125DA	White Cedar	
/35128DA	Willow	
/35130DA	Yew	
/35253DA	Yew Podocarpus	
	4-8 (50%, 90% WP) (1.39 lb/gal FlC)	Broadcast. Apply in the fall or spring before weeds emerge. May be diluted in 10 gallons of water.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/33058AA	Algerian Ivy (ground cover)	
33059AA	Baby's Tears (ground cover)	
/33086AA	Big Blue Lily Turf (ground cover)	
/33110AA	Bugleweed (ground cover)	
/33060AA	Ceanothus (ground cover)	
/33061AA	Cinquefoil (ground cover)	
/33130AA	Dwarf Coyotebrush (ground cover)	
/33030AA	English Ivy (ground cover)	
/33128AA	Gazania (ground cover)	
/33124AA	Ice Plant (ground cover)	
/33127AA	Juniper (ground cover)	
/33044AA	Periwinkle (ground cover)	
/33125AA	Stonecrop (ground cover)	
/33106AA	Strawberry (ornamental) (ground cover)	
	0.5-2.0 lb a.i./ 5,000 sq.ft (50%, 80%, 90% WP) (1.39, 4 lb/gal FlC)	Broadcast application to new and established plantings. For new plantings, apply after cuttings have rooted (usually 1 month after planting). For established plantings, apply in the fall, early winter, or spring before weeds emerge. Repeat treatment in 6 months.
	[MAI] 1.25 lb a.i./5,000 sq.ft (2.3% G)	Preplant application. Broadcast. Do not use where plants are to be grown from seed. Formulated with carbaryl.
/33017AA	Bermudagrass	
	0.5 lb a.i./5,000 sq.ft (50%, 90% WP) (4 lb/gal FlC)	Broadcast. Apply to established bermudagrass. Apply in the fall to control annual bluegrass and in the spring to control crabgrass. Make early spring applications while bermudagrass is still dormant.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/35042DA /35051DA /35068DA /35074DA /35098DA /35116DA	Cypress Fir Hemlock Larch Pine Spruce	General Information: These sites include: Baldcypress, Balsam-Fir, Douglas-Fir, Frasier Fir, Grand Fir, Noble Fir, Red Fir, White Fir, Rocky Mountain Douglas-Fir, Eastern Hemlock, Western Hemlock, Japanese Larch, Western Larch, Austrian Pine, Loblolly Pine, Lodgepole Pine, Longleaf Pine, Monterey Pine, Ponderosa Pine, Scotch Pine, Shortleaf Pine, Slash Pine, Sugar Pine, White Pine, Englemann Spruce, Norway Spruce, and White Spruce. If application is made 1 day before or within 2 days after seeding a second 10 pound active ingredient per acre treatment may be applied 6 weeks after seeding. For cypress and spruce apply after seedlings are 1 month old. Use only postplanting applications on Austrian Pine.
	2-10 (50%, 90% WP) (4 lb/gal FlC)	Broadcast application to nursery seedbeds. Apply 1 day prior to seeding to within 1 month after seeding and mulching. Apply 0.5 to 0.75 inch of water by overhead sprinkler irrigation. Work all weed growth into soil before application.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/33028AA	Dichondra	**General Information:** Do not use on grass lawns. Apply when foliage is dry.
	1.2 lb a.i./5,000 sq.ft (1.42% G) (50%, 80%, 90% WP) (1.39, 4 lb/gal FlC) [MAI] 1 lb a.i./5,000 sq.ft (3.44% G)	Preplant application to seedbeds or broadcast treatment to established dichondra. For preplant treatment prepare seedbed and rake in 0.5 inch deep before seeding. A second application may be made in 6 months. For established dichondra, apply in the spring before weeds germinate and again in the fall. Repeat application every 4 months. May be diluted with 2 to 10 gallons of water. May be formulated with monuron.
	[MAI] 1.00-1.25 lb a.i./5,000 sq.ft (2.3%, 2.65%, 5.3% G)	Preplant application to seedbeds or broadcast treatment to established dichondra. Apply throughout the year. Formulated with one or a combination of the following: neburon, monuron, and carbaryl.
	[MAI] 1 lb a.i./5,000 sq.ft (3.5% G)	Use limited to CA. Postemergence. Broadcast. Apply in winter, spring or fall to established dichondra. Make 2 applications, 6 to 8 weeks apart, to control emerged weeds. To control spurge and crabgrass both applications must be made before mid-March in southern CA, late March in the Interior Valley, and before mid--April in northern CA. Do not apply to newly seeded dichondra and do not plant dichondra seed sooner than 2 months after application. Formulated with neburon, monuron, and chloropyrifos.

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	AERIAL AND TANK MIX APPLICATIONS	
9001500 AAAAAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Peppers, Potatoes, Tomatoes
9900300 AAAAAAA	Tank Mix	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Peanut, Soybean, Sweet Potatoes, Tomatoes, Tobacco

Listing of Registered Pesticide Products by Formulation

&097.0001 97% technical chemical
diphenamid (036601)
045639-00127*
*jacket currently unavailable for review

&090.0002 90% formulation intermediate
diphenamid (036601)
045639-00108

&095.0002 95% formulation intermediate
diphenamic (036601)
045639-00120

&001.4204 1.42% granular
diphenamid (036601)
000557-01740

&002.3004 2.3% granular
diphenamid (036601) plus carbaryl (056801)
010942-00004

diphenamid (036601), monuron (035501) plus carbaryl (056801)
010942-00003

&002.6504 2.65% granular
diphenamid (036601) plus carbaryl (056801)
000538-00031*+
*jacket currently unavailable for review
+suspended

&003.4404 3.44% granular
diphenamid (036601) plus monuron (035501)
003234-00032

&003.5004 3.5% granular
diphenamid (036601), neburon (012001), monuron (035501) plus chloropyrifos (059101)
000538-00122

&005.0004 5% granular
diphenamid (036601)
(011440-00001) NC800032*
*jacket currently unavailable for review

&005.3004 5.3% granular
diphenamid (036601), neburon (012001) plus carbaryl (056801)
000538-00042

&250.0006 50% wettable powder
  diphenamid (036601)
    000070-00238   000192-00139   000226-00226   000264-00358
    002393-00345   002393-00438   045639-00107   045639-00111

    (045639-00107)   CA780050# CA780056 CA790107 NC800005#
    NC800006# SC800001# SC800002# VA800006
    VA800010
      #double parent label

&280.0006 80% wettable powder
  diphenamid (036601)
    002393-00346   023486-00049*
      *see auxiliary documentation

&290.0006 90% wettable powder
  diphenamid (036601)
    000070-00237   000226-00245   045639-00131   045639-00133

    (045639-00131)   CA780050# CA790180 NC800005# NC800006#
    SC800001# SC800002# VA800009 VA800011
      #double parent label

&218.3012 18.3% emulsifiable concentrate
  diphenamid (036601) plus dinoseb, triethanolamine salt (037506)
    045639-00118*
    *jacket currently unavailable for review

&215.4014 15.4% (1.39 lb/gal) flowable concentrate
  diphenamid (036601)
    000192-00140   045639-00117

&242.5014 42.5% (4 lb/gal) flowable concentrate
  diphenamid (036601)
    n01812-00282

9999999 State Label Registrations

  CA Reg. No.
    007001-07762   007159-08279   011093-07367   011149-04672

  NY Reg. No.
    038655-10441   038655-10444

DIPHENAMID

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
056801	carbaryl	--
059101	chloropyrifos	--
035501	monuron	--
012001	neburon	--

-- Use Common Name

DIPHENAMID

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
029901	chloramben	--
018301	chlorpropham	isopropyl N-(3-chlorophenyl) carbamate
037505	dinoseb	--
037506	dinoseb, triethanolamine salt	--
100201	isopropalin	--
035506	linuron	--
113501	metalaxyl	--
103001	napropamide	N,N-diethyl-2-(1-napthalenyloxy) propionamide
104201	oryzalin	--
041403	pebulate	S-propyl butylethylthiocarbamate
108501	pendimethalin	--
098901	trichlorfon	1,2-benzisothiazolin-3-one
036101	trifluralin	--

-- Use Common Name

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Diphenamid Standard

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00018842	Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499; Research Report CF-7501. (Unpublished study received May 8, 1971 under 1F1174; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by Ciba Agrochemical Co., Summit, N.J.; CDL:090973-B)
00026700	Holifield, E.; Barrow, K.; Clark, R.C.; et al. (1974) Residue: Enide 50W. (Unpublished study received Aug 1, 1974 under 1023-23; submitted by Upjohn Co., Kalamazoo, Mich.; CDL: 005407-C)
00029335	Upjohn Company (1966) Summary: Residue Analysis. (Unpublished study received Mar 3, 1966 under 1023-23; CDL:005473-A)
00031791	Stephenson, J.E.; Deloatch, F.; Majett, G.B. (1975) Summary of Residue Data for the Sequential Application of Vernam + Enide + Dinitro on Peanuts. (Unpublished study received Aug 11, 1976 under 476-2155; prepared in cooperation with Morse Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225431-B)
00035595	Holifield, E.L.; Hogan, W.H.; Stone, W.J.H.; et al. (1970) Residue Determination for Diphenamid and Desmethyldiphenamid on Peanut Hulls: Report No. 119-9760-17. (Unpublished study including report nos. 119-9760-18, 119-9760-19, 119-9760-24..., received Jun 12, 1970 under 0F0933; submitted by Upjohn Co., Kalamazoo, Mich.; CDL:091591-E)
00035596	Hogan, W.H.; Stone, W.J.H.; Holifield, E.L.; et al. (1970) Residue Determination for Diphenamid and Desmethyldiphenamid on Sweet Potatoes: Report No. 119-9760-14. (Unpublished study including report nos. 119-9760-15, 119-9760-20, 119-9760-21..., received Jun 12, 1970 under 0F0933; submitted by Upjohn Co., Kalamazoo, Mich.; CDL:091591-F)
00035601	Upjohn Company (1964) Stability of Diphenamid in Frozen Produce. (Unpublished study received Jun 12, 1970 under 0F0933; CDL: 091592-E)
00035602	Upjohn Company (1963) Stability of Diphenamid in Frozen Macerated Peanut. (Unpublished study received Jun 12, 1970 under 0F0933; CDL:091592-F)
00035603	Upjohn Company (1963) Stability of Diphenamid in Frozen Macerated Sweet Potato. (Unpublished study received Jun 12, 1970 under 0F0933; CDL:091592-G)

OFFICE OF PESTICIDE PROGRAMS
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MRID	CITATION
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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to ente into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following require items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ______________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	 Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468
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ATTACHMENT D

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________________________

Registrant's Name: ______________________________

and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient named under FIFRA sec. 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product,

OR

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________________________
and their registration number(s) is/are ______________________________

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA sec. 3(c)(2)(B).

Registrant's authorized representative: ______________________________
Signature

Dated: ____________________ ______________________________
(Typed)

50272-101

REPORT DOCUMENTATION PAGE	**1. REPORT NO.**	**2.**	**3. Recipient's Accession No.** PB88 113162/AS

4. Title and Subtitle

Guidance for the Registration of Pesticide Products Containing DIPHENAMID as the Active Ingredient.

5. Report Date

ISSUED June 1987

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(C)

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Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how th register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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(See ANSI-Z39.18) See Instructions on Reverse

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